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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/799,514 | 03/12/2004 | Francois Spertini | 30985/41486 | 8487 |

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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT PAPER NUMBER

1644

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,514

Applicant(s)

SPERTINI ET AL.

Examiner

Nora M. Rooney

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 55-70 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 55-65, drawn to a method for generating an improved composition of contiguous overlapping peptide fragments (COPs) for a selected polypeptide allergen comprising: determining COPs by conducting a structural analysis of the selected allergen and selecting one or more separation sites; producing said candidate COPs; and screening said candidate COPs by selecting COPs characterized by having a T cell stimulating activity and an IgE binding activity, classified in Class 530, subclass 333.

II. Claim 66, drawn to a method for generating an improved chimeric allergen useful in diagnostic use or in inducing tolerance to two or more selected polypeptide allergens comprising: determining candidate peptide fragments of two or more polypeptide allergens by conducting a structural analysis of the selected allergens and selecting one or more separation sites in each allergen; producing said candidate peptide fragments; and screening said candidate peptide fragments by selecting candidate peptide fragments characterized by having a T cell stimulating activity and an IgE binding activity; classified in Class 530, subclass 333.

III. Claim 67, drawn to a method for generating an improved chimeric allergen useful in diagnostic use or in inducing tolerance to two or more selected polypeptide allergens comprising: determining candidate peptide fragments of two or more polypeptide allergens by conducting a structural analysis of the selected allergens and selecting one or more separation sites in each allergen; producing a candidate chimeric allergen at least one candidate peptide fragments from each allergen; and screening said candidate chimeric allergen by selecting candidate chimeric allergens characterized by having a T cell stimulating activity and an IgE binding activity; classified in Class 530, subclass 333.

IV. Claim 68, drawn to a composition of contiguous overlapping peptide fragments selected by the method for generating an improved composition of contiguous overlapping peptide fragments (COPs) for a selected polypeptide allergen comprising: determining COPs by conducting a structural analysis of the selected allergen and selecting one or more separation sites; producing said candidate COPs; and screening said candidate COPs by selecting COPs characterized by having a T cell stimulating activity and an IgE binding activity, classified in Class 424, subclass 184.1 and Class 514, subclass 2.

V. Claim 69, drawn to a chimeric allergen produced according to the method for generating an improved chimeric allergen useful in diagnostic use or in inducing tolerance to two or more selected polypeptide allergens comprising: determining candidate peptide fragments of two or more polypeptide allergens by conducting a structural analysis of the selected allergens and selecting one or more separation sites in each allergen; producing said candidate peptide fragments; and screening said candidate peptide fragments by selecting candidate peptide fragments characterized by having a T cell stimulating activity and an IgE binding activity, classified in Class 514, subclass 2 and Class 530, subclass 350.

VI. Claim 70, drawn to a chimeric allergen produced according to the method for generating an improved chimeric allergen useful in diagnostic use or in inducing tolerance to two or more selected polypeptide allergens comprising: determining candidate peptide fragments of two or more polypeptide allergens by conducting a structural analysis of the selected allergens and selecting one or more separation sites in each allergen; producing a candidate chimeric allergen at least one candidate peptide fragments from each allergen; and screening said candidate chimeric allergen by selecting candidate chimeric allergens characterized by having a T cell stimulating activity and an IgE binding activity, classified in Class 424, subclass 184.1 and Class 530, subclass 350.

2. Groups IV-V are different products. The composition of contiguous overlapping peptide fragments of Group IV differs from the chimeric allergens of Groups V and VI, that are each

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produced by a different method, with respect to their structures, modes of action and physicochemical properties; therefore each product is patentably distinct.

3. Groups I-III and IV-VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the allergens of Groups V and VI and the composition of Group IV product can be used for monoclonal antibody generation and sequencing.

4. Groups I-III are different methods. The methods for generating an improved composition of contiguous overlapping peptide fragments (COPs) for a selected polypeptide allergen of Group I, generating an improved chimeric allergen useful in diagnostic use or in inducing tolerance to two or more selected polypeptide allergens of Group II and generating an improved chimeric allergen useful in diagnostic use or in inducing tolerance to two or more selected polypeptide allergens of Group III differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

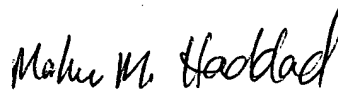
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A

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message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 29, 2006


MAHER M. HADDAD
PATENT EXAMINER

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600